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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/656,797

09/04/2003

Niel F. Starksen

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25226 7590 02/06/2007  
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EXAMINER

ANDERSEN, MICHAEL T

ART UNIT

PAPER NUMBER

3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/06/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/656,797

Applicant(s)

STARKSEN, NIEL F.

Examiner

M. Thomas Andersen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-34, 37-45, 51, 52 and 54-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-36, 46-50, 53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/28/2006, 12/13/2006, 1/18/2007.

### **DETAILED ACTION**

Acknowledgement is made of the response filed 11/21/2006, to the non-final Office action dated 8/22/2006.

#### ***Specification***

Acknowledgement is made to the amendment of the specification. The objection to the specification is thus withdrawn.

#### ***Information Disclosure Statement***

The information disclosure statements (IDS) received on 3/16/2006, 9/12/2005, 11/22/2004 and 12/11/2003 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

#### ***Response to Arguments***

Applicant's arguments filed 11/21/2006 have been fully considered but they are not persuasive. Applicant has traversed the rejection and has not amended the claims. Applicant has argued that independent claim 35 requires that the stabilizing member be positionable under one or more leaflets of a valve of the heart "to engage a length of the annulus along an intersection between at least one leaflet and an interior ventricular wall of the hear." See claim 35; Remarks dated 11/21/2006, page 2. Applicant further argues that "Taheri simply does not teach a stabilizing device that is positionable under one or more leaflets of the heart to engage a length of the annulus along an intersection between at least one leaflet and an interior ventricular wall of the heart. . . . Instead,

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Taheri teaches method and apparatuses for stapling graft material to the aortic wall while preserving the patency of the aortic branch orifices." Id.

In regard to the rejection under 35 U.S.C. 103(a), Applicant argues that "The Office Action fails to set forth a *prima facie* case of obviousness for at least the reason that the combination of Taheri and Brock does not teach or suggest all the claim limitations." Id. at p.3.

In response to these arguments, the examiner subtly points out that the claims in question are apparatus claims, not method claims. In the last Office action it was stated that Taheri's device "is capable of being positioned under one or more leaflets of a valve of the heart to engage a length of the annuls along an intersection between at least one leaflet and an interior ventricular wall of the heart." Office action dated 8/22/2006, page 3. If the prior art structure is capable of performing the intended use, then it meets the claim.

The previous rejection follows:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **35-36** are rejected under 35 U.S.C. 102(b) as being anticipated by **Taheri**, U.S. Patent No. **5,843,169**. Taheri discloses an apparatus and method for stapling using a balloon catheter.

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Claim 35: Figure 1a of Taheri discloses an elongate body 11 and a stabilizing member 15 at the distal end that is capable of being positioned under one or more leaflets of a valve of the heart to engage a length of the annulus along an intersection between at least one leaflet and an interior ventricular wall of the heart.

Claim 36: The elongate member 11 can be said to comprise a rigid shaft.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 46-50 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taheri, as applied to claim 35 above, in view of Brock et al., US 2002/0087169 (hereinafter "**Brock**"). Brock discloses a flexible instrument to deliver anchors using a balloon.

Claim 46: Taheri further discloses a semicircular housing (figure 5b) and an expandable balloon, but does not appear to disclose a plurality of *tethered* anchors disposed within the housing. Brock discloses in figures 36-37 a plurality of tethered anchors disposed within a circular housing. A semi-circular housing is considered an obvious variation of a circular housing, particularly in view of Brock. Brock and Taheri both involve inserting anchors into tissue using a balloon member. Further, a semi-circular housing would take up less space and would provide for a less-invasive surgery. It therefore would have been obvious to combine Taheri with Brock.

Claim **47**: The hooks in Taheri or Brock can be considered curved hooks or straight barbed hooks.

Claims **48-49**: Brock further discloses a pivot mandrel 409 around which the hooks pivot to engage annular tissue.

Claim **50**: Brock further discloses an inflation actuator for inflating the expandable balloon; a release actuator for releasing the anchors from the housing; and a cinching actuator for cinching a tether coupled with the tethered anchors to reduce a diameter of the valve annulus. See e.g. paragraphs 0277 through 0283.

Claim **53**: The hooks in Brock can be considered deployable mechanical support structures for constricting the valve annulus.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Thomas Andersen whose telephone number is (571) 272-8024. The examiner can normally be reached on M-F 8AM-4:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Thomas Andersen

January 25, 2007



MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER